Propylene Carbonate - Comments of Environmental Defense

(Submitted via Internet 8/28/02)

Environmental Defense appreciates this opportunity to submit comments on the Robust Summary/Test Plan for Propylene Carbonate (CAS # 108-32-7).

The Propylene Carbonate/t-Butyl Alcohol HPV Committee and its member companies Lyondell Chemical Company and Huntsman Corporation have developed and submitted a Robust Summary/Test Plan for Propylene Carbonate (PC). Though PC has a multitude of uses, most of which are described in the Test Plan, it has been the subject of relatively little toxicological research published in the open literature. The lack of toxicological research can probably be attributed to the fact that available data indicate this compound has low toxicity. Also, PC does not persist in the environment, it is not genotoxic and it does not appear to induce developmental or reproductive toxicity. Most of the existing data presented in the Robust Summary are taken from unpublished reports prepared by contract laboratories. Studies described appear to be well designed and most were conducted under GLP.

Regrettably, the Test Plan and Robust Summary provides no more than a cursory discussion of the data. While the documents generally meet the minimum criteria of the HPV program, given PC's potential for exposure to the general public it would seem to be in the best interest of manufactures of PC to make information on its apparent low toxicity and lack of persistence in the environment as readily available to the public as possible. Thus, the Propylene Carbonate/t-Butyl Alcohol HPV Committee and its member companies should refer to Robust Summary/Test Plans submitted for other chemicals under the HPV program. Many Test Plans/Robust Summaries do a much better job of describing uses and sources of exposure, and also provide more thorough discussions of significant data on toxicity.

For example, although the most significant source of human exposure to PC may well result from its use in cosmetics, this use is mentioned only in passing in the Test Plan. Neither the Test Plan nor the Robust Summary makes any reference to the "Final Report on the Safety Assessment of Propylene Carbonate," published in 1987, which addresses PC use in cosmetics. Nor does either document present the structural formula for PC as requested. Results of computer modeling to predict fugacity are not discussed in the Test Plan. Although we consider it appropriate to use data on butylene carbonate to predict the acute toxicity of fish and daphnia, these results should be referenced. Moreover, while we agree with the conclusion that butylene carbonate is "an acceptable surrogate for propylene carbonate because of similar physical-chemical properties," it would be helpful to spell out the reasoning behind this conclusion.

In addition, while not strictly required for HPV purposes, the Robust Summary would be strengthened by including the following two references to publicly available documents:

1. Anonymous. Final Report on the Safety Assessment of Propylene Carbonate, J. American College of Toxicol. 6: 23-51, 1987

2. Anonymous. Environmental Profile for Propylene Carbonate, Govt. Reports Announcements & Index, Issue 01

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Karen Florini
Senior Attorney, Environmental Defense